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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,064	12/12/2003	Veronique Barban	API-02-14-US	1266

7590

09/27/2005

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EXAMINER
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CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/735,064	BARBAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 16, 17, 19-21 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15, 18, 22, 23, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. This application is now pending in view of the petition to revive, granted on September 16, 2005. Applicant elected group II with traverse, claims 15, 18, 22, 23, 27 and 28, drawn to ALVAC viruses and composition thereof. Claims 1-14, 16, 17, 19-21 and 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant argues that because the two groups are related as product and process of making, no serious burden would be placed on the examiner to search both groups. In response to Applicant's arguments, a search for both the product and a method of making that product would be a serious burden, as previously set forth in the restriction requirement of January 5, 2005. Applicant has not particularly pointed out the specific reason why the reasoning provided in the restriction requirement is not adequate to establish burden of search. Therefore, the restriction requirement is deemed proper and made FINAL.

### ***Claim Objections***

2. Claim 18 is objected to for depending from itself. Correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 18 is dependent on itself (claim 18) and also dependent on claim 17. Claim

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17 is dependent on itself (claim 17). The metes and bounds of claim 18 are unclear, however in the interests of compact prosecution, the subject matter of claim 18 will be interpreted as ALVAC(2). Correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 18, 22, 23, 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the ALVAC and ALVAC(2) strains of canarypoxvirus are required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of ALVAC and ALVAC(2). See 37 CFR 1.802. One cannot practice the claimed invention without ALVAC and ALVAC(2). Therefore, access to ALVAC and ALVAC(2) is required to practice the invention. The specification does not provide a repeatable method for ALVAC and ALVAC(2)

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without access to the ALVAC and ALVAC(2) and they do not appear to be readily available material.

It is noted that ALVAC has been deposited at the ATCC, however further information is required to satisfy the enablement requirements (see below). Deposit of ALVAC(2) in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strain would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

**If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.**

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

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(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

### *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 18, 22, 23, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Paoletti et al. (US 5,833,975, "Paoletti"). The claims are drawn to a composition comprising ALVAC (Albany vaccine), a canarypoxvirus. Also claimed are compositions comprising ALVAC vectors, comprising heterologous genes encoding a human tumor antigen, an antigen derived from a human pathogen or a fragment thereof. The composition is used as a medicament for the treatment of human disease. Also claimed is ALVAC(2), which differs from ALVAC in that the genome comprises the vaccinia E3L and K3L genes under the control of vaccinia promoters (specification, page 4, last paragraph).

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Paoletti discloses canarypox viruses expressing tumor-associated antigen DNA (abstract). Specifically, the vector is ALVAC or ALVAC(2) (see instant specification, page 4, lines 28-30). The vectors are inactivated and administered with carriers (col. 8, lines 21-24, and col. 13, lines 27-47). Other genes are used in the vectors besides tumor antigens. Paoletti discloses the use of DNA from pathogens (col. 8, lines 34-46).

Regarding the limitations in the claims as to their method of production, these limitations do not lend patentability. As Applicant is aware, product-by-process claims for prior art purposes are treated only with regard to the actual components and not their intended uses. The exception to this is if the method of production results in a structurally and functionally distinct product than that of the prior art. In this case, the burden is on Applicant to prove that the method by which Applicant makes ALVAC and ALVAC(2) results in a structurally and functionally different product than Paoletti's ALVAC and ALVAC(2) vaccine.

6. Claims 15, 22, 23, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Snow (*Bay Area Reporter*, National Institutes of Health: ALVAC Prime and Boost, HIV Vaccine Handbook, Approaches, 1998, pages 201-208). The claims are summarized above. Snow discloses the general knowledge available to the public regarding ALVAC engineered to express HIV envelope glycoprotein gp120 (page 202). Therefore, the claims are anticipated by Snow's disclosure of the ALVAC/gp120 immunogenic composition administered to humans for treatment of HIV.


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*Conclusion*

7. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
September 23, 2005